SERVICE

This pump is designed to be highly reliable. As with any electro-mechanical device, minor problems may occur. To inquire about service for your pump or charger, call the number below. Be prepared to provide device name, serial number found on back and specifics of problem.

Pump	Service
Companion™ and Charger	

BEFORE CALLING, DO A FEW SIMPLE CHECKS:

1. *Check for proper electrical connection. (Is pump connected to mains? Is electrical outlet functioning? Is battery properly charged?)*

2. *If electrical outlet usage is intended, be sure pump is properly positioned within charger.*

3. *Be sure a FLEXIFLO™ Companion™ Pump Set is being used, and that cassette is properly seated in cassette cavity.*

4. Check visual display, and correct situation as indicated.

The Abbott Medical Nutritional System

A total commitment to enteral nutrition.

ABBOTT LABORATORIES
North Chicago, IL 60064

P/N 200099 (3/97)
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Patents Pending

FLEXIFLO™ Companion™

Enteral Nutrition Pump

OPERATING MANUAL

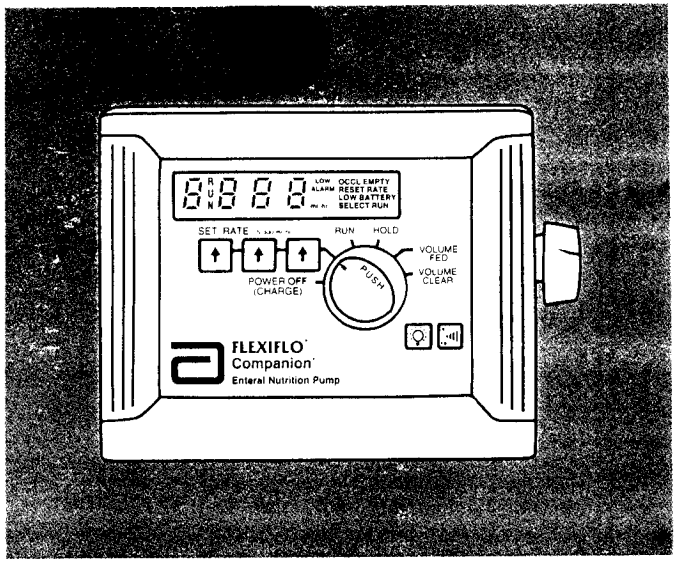


TABLE OF CONTENTS

	PAGE
Pump Characteristics	3
Paediatric Use	3
Precautions	3
Illustrations	4-5
Control Settings	6
Visual Displays and Audio Alarms	6-7
Special Features and Companion Pump Sets	8
Instructions for Use	9-11
Battery Operation	11
Checking Pump Accuracy	12
Cleaning and Maintenance	12
Ambulatory Transporter	13
Specifications	14
Storage	14
Limited Warranty	15
Service	16

CE 0197

This device complies with the requirements of
Council Directive 93/42/EEC

PUMP CHARACTERISTICS

Uniquely designed and constructed, the FLEXIFLO™ Companion Enteral Nutrition Pump is a volumetric infusion pump that uses a specially designed administration set, including a cassette with bellows to deliver measured amounts of enteral feed. The pump will operate on AC power or battery. The fluid delivery system and safety alarms function when the pump is used by an ambulatory patient or is mounted on an IV pole. The volume monitoring device does not depend on drop counting, so the pump is more versatile in adapting to patient activities.

The pump is microprocessor (computer) controlled, which provides accurate delivery rates, easy-to-read displays, and simple controls.

The Companion Pump offers these features:

1) Alarms:
   - occlusion
   - empty container/missing or improperly loaded cassette
   - low battery
   - start reminder
2) Accuracy to ± 10% (5 to 300 ml/hr)
3) 8-hour battery operation at 150 ml/hr, when fully charged
4) Fluid flow and fluid monitoring independent of pump position (no drop counting)
5) Adjustable alarm volume for low or high setting
6) Flow rate selection of 5 to 300 ml/hr in 1-ml/hr increments
7) VOLUME FED accumulation display
8) Automatic retention of values while operating or on hold
9) User-friendly operating controls
10) Small and lightweight
11) Simple setup (one-hand cassette loading)
12) "Backlit" visual display for easier viewing in a darkened room
13) Self-test capability

PAEDIATRIC USE

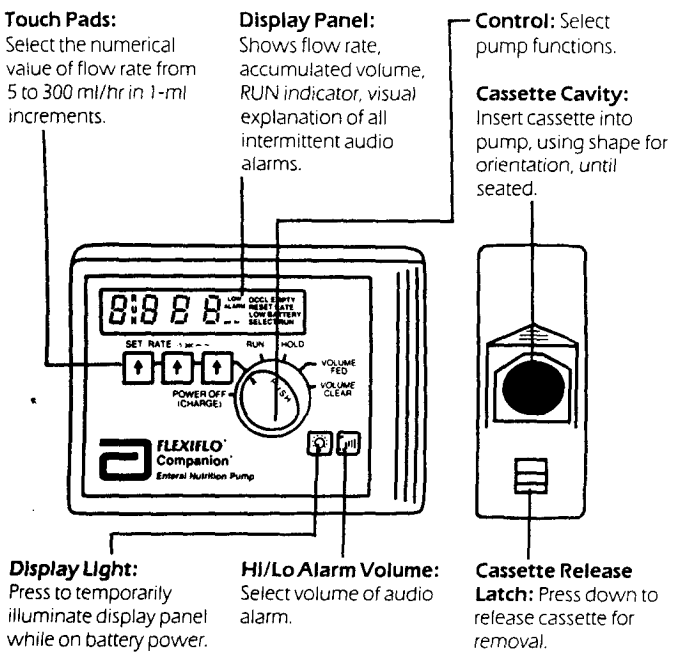
This pump is not recommended for feeding newborn infants or infants in a neonatal intensive care unit. All enteral pumps may bolus-feed small amounts, which is an important consideration when feeding volume-sensitive patients. The FLEXIFLO Companion Pump should normally be used only for children 12 months of age or older, and only if the rate of feeding is 25 ml/hr or greater. In these cases, small-volume containers should be used that contain a volume of product no more than four times the hourly feeding rate.

PRECAUTIONS

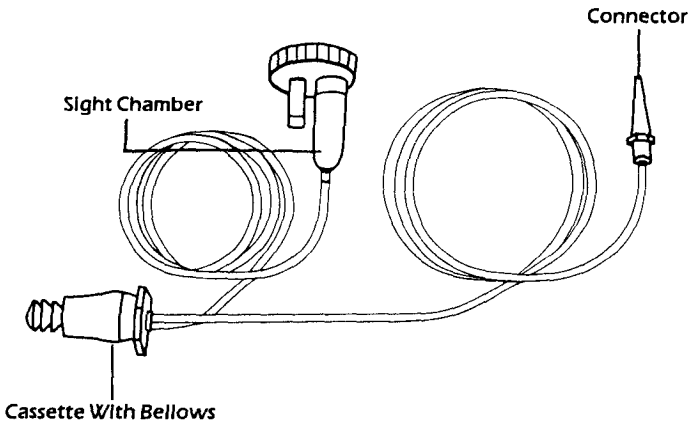
- **NOT FOR PARENTERAL USE.**
- Connect new pump to mains for 15 hours to charge battery before operating in battery mode.
- Confirm proper placement and function of patient's enteral feeding tube (nasogastric, jejunostomy, gastrostomy, etc.) before initiating feeding.

FLEXIFLO® Companion®
ENTERAL NUTRITION PUMP
ILLUSTRATIONS

Pump

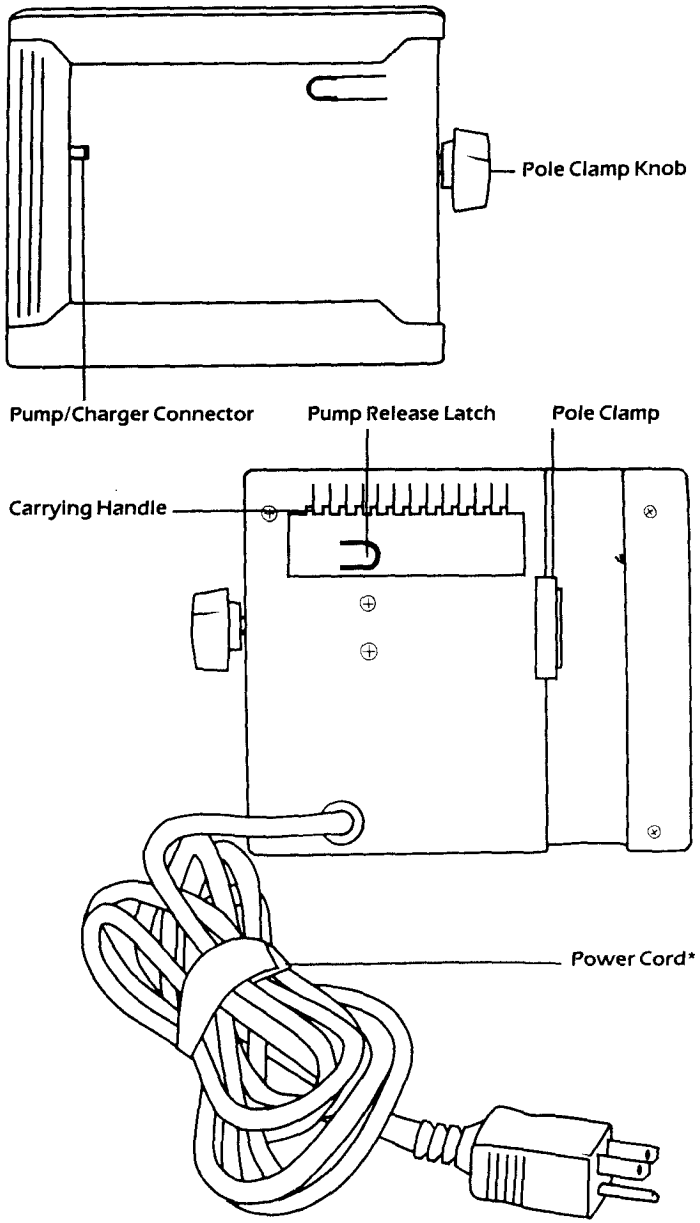

Touch Pads: Select the numerical value of flow rate from 5 to 300 ml/hr in 1-ml increments.
Display Panel: Shows flow rate, accumulated volume, RUN indicator, visual explanation of all intermittent audio alarms.
Control: Select pump functions.
Cassette Cavity: Insert cassette into pump, using shape for orientation, until seated.
SET RATE
RUN
HOLD
VOLUME FED
VOLUME CLEAR
POWER OFF (CHARGE)
FLEXIFLO Companion Enteral Nutrition Pump
Display Light: Press to temporarily illuminate display panel while on battery power.
Hi/Lo Alarm Volume: Select volume of audio alarm.
Cassette Release Latch: Press down to release cassette for removal.

Pump Set*



*Sets are also available with a piercing pin (except in the U.K.) and with pre-attached feeding containers for hospital use (1,000 ml) or ambulatory use (500 ml).

Charger



*Note: Mains Power Cord and Plug will differ depending on local electrical standards.

CONTROL SETTINGS

POWER OFF (Charge): This setting stops all pump functions and erases all memory. Battery charges whenever connected to mains.

SET RATE: This setting allows flow rate to be set (5 to 300 ml/hr in 1-ml increments) by using the touch pads (active only in this mode). No pumping action occurs in this mode.

RUN: This is the ONLY setting that activates pumping action. Visual display shows flashing RUN and rate of flow in ml/hr.

HOLD: This setting stops pumping action and any audio alarm without erasing previous commands or memory functions. HOLD is used when correcting an alarm condition, or whenever temporary cessation of pumping action is desired.

VOLUME FED: This setting stops pumping action and displays accumulated numerical value of volume fed in ml since pump power was turned on, or volume clear was activated. NOTE: If 9999 ml is fed without turning off pump, numerical value turns to 0000 and a new accumulation begins.

VOLUME CLEAR: This setting stops pumping action and automatically clears to zero any accumulated numerical value of volume fed.

VISUAL DISPLAYS AND AUDIO ALARMS

Visual Displays

Control Setting	Visual Display	Status
POWER OFF (Charge)	None	Pump is charging if connected to mains supply.
SET RATE	Previous flow rate or 000 ml/hr	Push touch pads to change or set rate.
RUN	Numerical rate in ml/hr and RUN	Pump is running.
HOLD	Existing flow rate or 000 ml/hr Any visual alarm display will remain visible	Audio alarm stops; memory retained. No pumping action.
VOLUME FED	Numerical value of accumulated volume fed in ml	No pumping action.
VOLUME CLEAR	Numerical value of accumulated volume fed is automatically cleared to 0000 ml	No pumping action. Memory of flow rate retained.

Audio Alarms

Intermittent audio alarms are always accompanied by a visual message on display panel indicating cause of alarm. The visual display LOW ALARM indicates alarm volume is low. If louder alarm volume is desired, press volume switch to change alarm audio level.

Visual Display	Cause of Audio Alarm	Action
OCCL	Flow has stopped	Turn control to HOLD. Check fluid container, pump set tubing and patient's indwelling feeding tube for flow restriction.
EMPTY	Empty feeding container or improperly seated cassette.	Turn control to HOLD. Assure that cassette is properly seated. If container is empty, provide new feed or turn control to POWER OFF if no additional feeding is desired.
SELECT RUN	Pump is in setting other than POWER OFF or RUN for longer than 5 minutes	• If pumping is desired turn control to RUN. • If additional time is desired in HOLD, turn control to RUN and then to hold. Alarm will sound again in 5 minutes. • If feeding is completed turn control to POWER OFF.
RESET RATE	Flow rate selected is less than 5 ml/hr	Turn control to SET RATE. Select rate of flow from 5 to 300 ml/hr.
LOW BATTERY	Approximately 30 minutes of battery power remain.	Turn control to HOLD, then back to RUN to stop audio alarm. Pump should be seated in charger and connected to mains.

NOTE: In case microprocessor or motor malfunctions, pump will stop pumping action, all visual displays will cease, and a *continuous* audio alarm will be sounded. Continuous alarm will not cease even if pump control is turned to HOLD. If F1 appears when the pump is turned on, the microprocessor is damaged or detects a malfunction. TURN PUMP CONTROL TO POWER OFF. SERVICING IS REQUIRED.

SPECIAL FEATURES

Small Size: The Companion Pump is small and lightweight. The pump weighs 0.7 kg; the charger weighs 1.1 kg. With the FLEXIFLO™ Companion™ Ambulatory Transporter, a patient can easily carry the pump and up to 500 ml of enteral feed during routine activities.

Position Does Not Affect Operation: The Companion Pump fluid delivery and alarm systems will function when the pump is in any position that might be normal for ambulatory or non-IV pole use – a real advantage for ambulatory patients.

Easy, 1-Hand Setup: One hand is usually all that is needed for setup, priming and seating of the cassette and setting the control. The setup is easy to learn and easy to teach to staff and patient.

Self-Test Procedure: Each time the pump is turned on, the microprocessor initiates a self-test procedure. Audio alarm, visual displays, and readout (8888) will turn on for 5 seconds. If the self-test fails, F1 will appear. **DO NOT USE THE PUMP. SERVICING IS REQUIRED.**

Ambulatory or I.V. Pole Use: The Companion Pump can be used in an ambulatory mode or with the charger on an I.V. Pole.

Enteral Feeding Sets: The following Enteral Sets are available*. They are disposable sets for single use only. Sets other than FLEXIFLO™ Companion™ Enteral Pump Sets are not suitable for use.

List 0071 – FLEXIFLO Companion Enteral Pump Set with Pre-attached 1 liter bag.

List 0086 – FLEXIFLO Companion Enteral Pump Set with 40mm Screw Cap.

List 0088 – FLEXIFLO Companion Enteral Pump Set with Piercing Pin.

List 0507 – FLEXIFLO Companion Ambulatory Enteral Pump Set with Pre-attached Feeding Bag.

List G304 – FLEXIFLO Companion Enteral Pump Set with 40mm Screw Cap and Female Connector.

List G415 – FLEXIFLO Companion Enteral Pump Set with Pre-attached 1 liter bag.

*Set availability may differ in some countries. Please contact your local Abbott Representative for information.

Pump/Charger Connection:

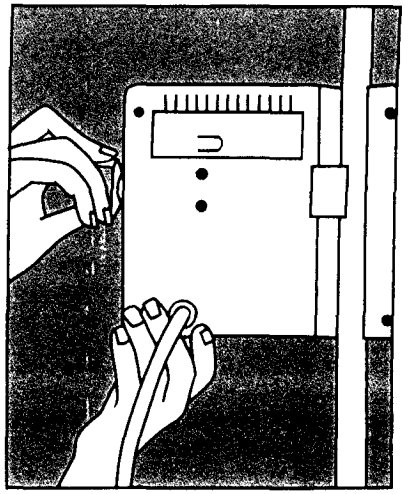
To Separate: When properly seated, the pump is held firmly within the charger. In order to separate pump and charger, locate pump release latch on back of charger within handle cavity. Pull pump toward opening while pressing latch in the same direction until pump is free. Grasp pump securely to withdraw it from charger.

To Reconnect: With pump display panel facing outward, slide pump into charger until it locks into position.

Ambulatory or I.V. Pole Use: The Companion Pump can be used in an ambulatory mode or with the charger on an I.V. Pole.

INSTRUCTIONS FOR USE

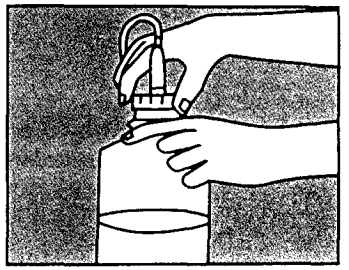
1. Attach to, or place on, appropriate feeding stand. If IV pole is used, be sure pump is properly seated in charger, and then clamp charger to pole.

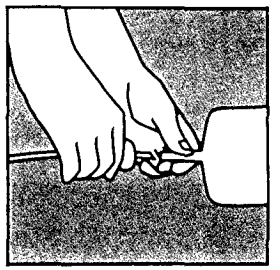


2. Connect cord to earthed mains if power is available. **NOTE: If quality of Earth grounding source is in doubt, use battery power.**

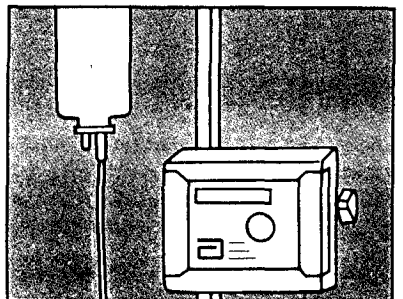
NOTE: When LOW BATTERY message appears, pump will run for approximately 30 minutes before shutting down completely. However, the pump can be used on AC power at this time. When fully charged, pump can operate on battery power for 8 hours. A new pump should be connected to a properly earthed mains for 15 hours before initial use on battery power, to assure full battery charge.

3. Fill feeding container with enteral feed. If a glass bottle is used, place bottle in provided suspension bag. Attach Companion Pump Set securely onto filled enteral nutrition container, if it is not preattached.



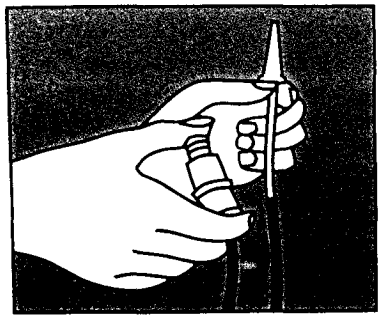


4. Suspend container to side of or behind pump with sight chamber at or above level of pump.



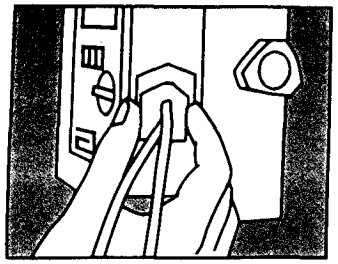
5. Squeeze sight chamber ½ full.

6. Remove cap from connector at distal end of pump set tubing. Compress bellows of cassette repeatedly (2 strokes/second) until fluid has expelled air from cassette and tubing. NOTE: Leaving 2 to 3 inches of tubing near adapter unprimed will avoid product dripping during setup.

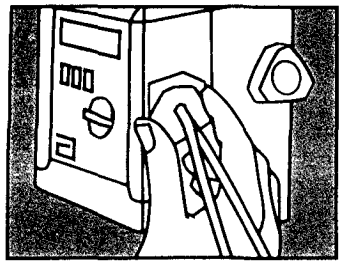


7. CONFIRM PROPER PLACEMENT AND FUNCTION OF PATIENT'S ENTERAL FEEDING TUBE (NASOGASTRIC, JEJUNOSTOMY, GASTROSTOMY, ETC). Attach connector to enteral feeding tube.

8. Insert cassette into pump, using shape for orientation. Press until cassette clicks into place. Grasp base of cassette tubing and pull gently to confirm that cassette is seated.

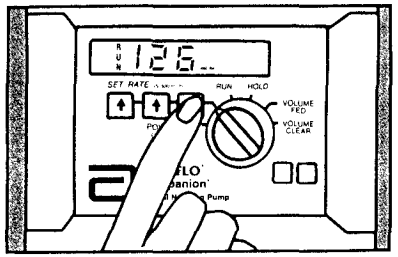


RIGHT

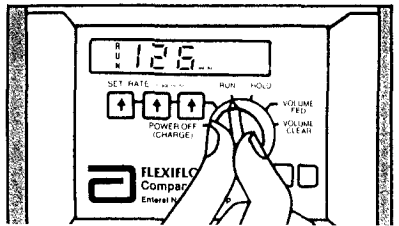


WRONG

9. Push and then turn control to SET RATE and select flow rate from 5 to 300 ml by pressing touch pads.



10. Turn pump control to RUN to start feeding. If cassette is not properly seated, the EMPTY alarm will sound after a short delay.



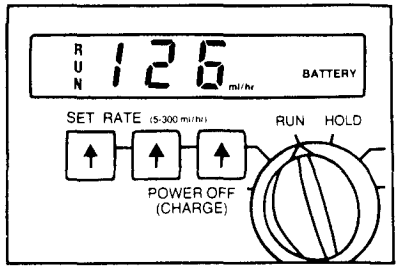
11. When feeding is completed, turn control to HOLD or POWER OFF. (If pump is switched to POWER OFF, it loses memory of RATE and VOLUME FED.)

12. When desired, disconnect pump set tubing from patient's enteral feeding tube, release cassette from pump by pressing release latch downward, and discard set and container.

PRECAUTIONS: The pump set and container should be replaced as needed, or at least every 24 hours, to avoid product contamination problems. For single patient use only.

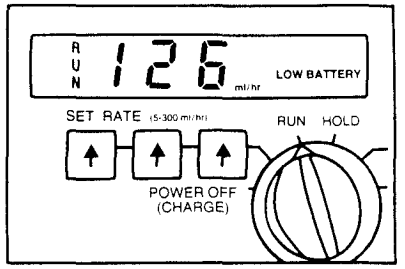
BATTERY OPERATION

1. If battery power is in use, BATTERY is visually displayed.



2. While pumping in battery mode, the LCD display light will turn off after a few minutes to save power. Press the light symbol in the lower right corner of the pump front to turn on the LCD display light.

3. LOW BATTERY flashing display indicates battery voltage is low. Pump should be connected to the mains as soon as possible. The pump will run for approximately 30 minutes after LOW BATTERY alarm first appears before it shuts down completely.



4. Pump can be used while battery is recharging.

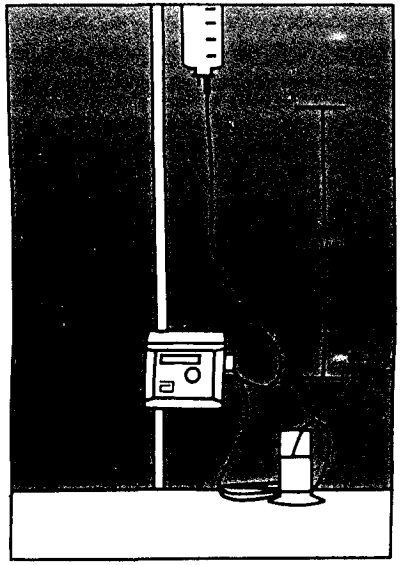
5. To charge pump, seat in charger and connect charger to properly earthed mains outlet for 15 hours. This should be done as soon as LOW BATTERY display appears. To ensure maximum battery capacity, keep pump connected to a properly earthed mains when it will not be used for an extended period of time. Battery will charge in any control setting, including OFF, when connected to mains. No other maintenance is required unless the battery fails. In that case, refer to qualified service personnel.

NOTE: A new pump should be charged for 15 hours before initial use on battery power, to assure full battery charge.

CHECKING PUMP ACCURACY

Fluid head height and viscosity are two variables that can affect flow rate. To check flow rate, use the following procedure: Be sure to use a graduated cylinder for volume measurement – not an enteral container. Using Ensure™ or Osmolite™, fill the container and set up pump according to instructions. Start the pump and let it run for 15 minutes. Then run product into graduated cylinder for 1 hour and compare to rate set on pump. If flow rate is incorrect, try a new pump set and repeat procedure.

Refer to SPECIFICATIONS for accuracy rate.



CLEANING AND MAINTENANCE

The pump and charger are specially designed for easy cleaning. The outside surfaces can be cleaned with warm, soapy water. For trouble-free operation, the surfaces should be cleaned immediately after spills occur.

The cassette cavity can be cleaned with a cotton swab or soft cloth and warm, soapy water. (Do not clean pump cavity with alcohol.) Dry thoroughly. Be sure no soap film or residue is left in the cassette cavity.

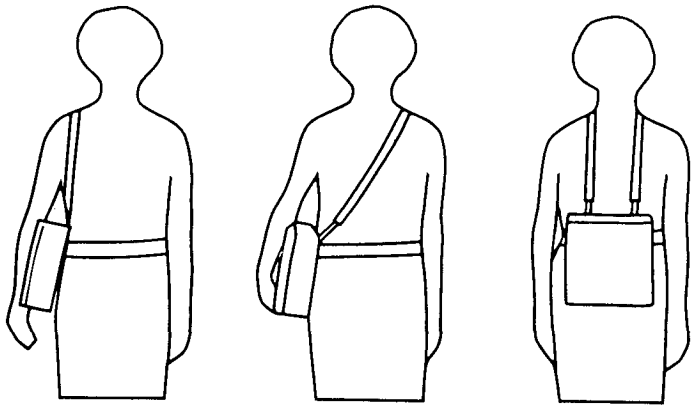
NOTE: DO NOT SUBMERGE OR AUTOCLAVE THE PUMP OR CHARGER.

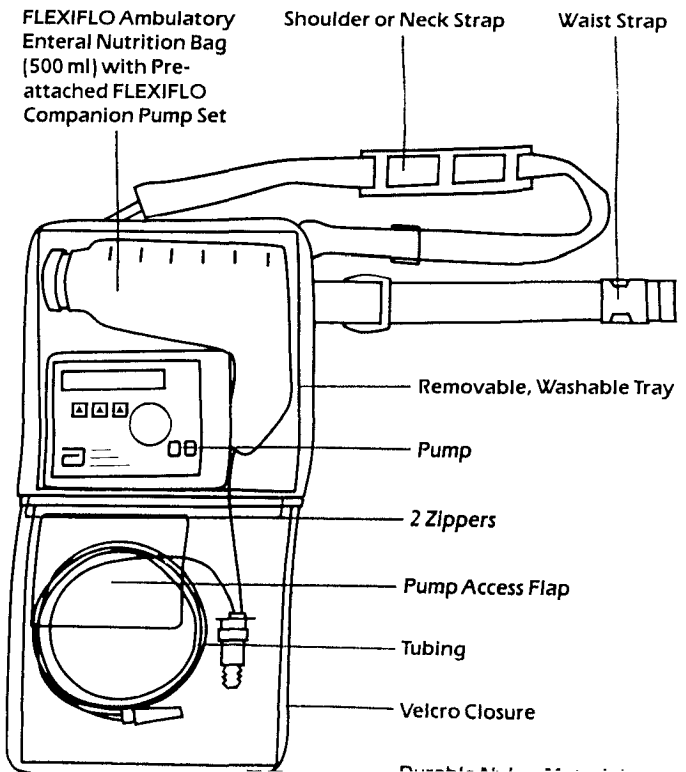
NO OTHER MAINTENANCE IS REQUIRED.
Service, if required should be performed by trained service representatives.

A Technical Service Manual is available.

FLEXIFLO™ Companion™ AMBULATORY TRANSPORTER

Ambulatory transporter enables patient to carry pump, bag and tubing without an IV pole.





SPECIFICATIONS

Power	Europe/Australia	Canada
Voltage:	220 to 240 V,~ 50 Hz, 1 Phase	120 VAC, 60 Hz, 1 Phase
Power:	2 watts (25mA)	2 watts (25mA)
Fuse:	T 100 mA, 5 x 20 mm	1 AMP, 3AG type
Line Cord:	Hospital grade (2.5m), detachable from charger	Hospital grade (2.5m),
Leakage:	Less than 100 microamps	Less than 100 microamps

Mechanical	Pump Only	Pump With Charger
Height:	10.9 cm	15.2 cm
Width:	15.2 cm	17.0 cm
Depth:	4.3 cm	8.3 cm
Weight:	0.7 kg	1.1 kg

Operational Specifications

Flow Rates

Range:	5 to 300 ml/hr
Increments:	1 ml/hr
Accuracy:	± 10% with measured flow rates of 1 Litre of enteral product from 5 to 300 ml/hr using Companion Pump Set at zero back pressure (atmospheric).
Pressure:	Pumps against 168 kPa (24psi) (mean) back pressure before occlusion alarm.

Battery Operation

Type:	1.0 Ah rechargeable sealed lead-acid.
Voltage:	4V; recharge rate: 1½ hours for every 1 hour of battery use.
Operating Time:	When fully charged, 8 hours at 150 ml/hr.

Standards:

Europe/Australia

Meets the IEC 601-1 Standards for:
Class I: (Mains supply equipment using protective earth.)
⍓ Type BF: (Type B Equipment with an F-Type Isolated (Floating) Applied Part.)
Drip Proof: (Equipment protected against ingress of falling liquid.)
⚠ Attention, consult accompanying documents.

Canada

Meets the requirements of CSA Standard C22.2 No. 125, Risk Class 2G. LR 83053.

STORAGE

The pump should be stored away from excessive temperatures or humidity. When pump will not be used for an extended period of time, keep it connected to mains to ensure maximum battery capacity.

LIMITED WARRANTY

Abbott warrants the FLEXIFLO™ Companion™ Enteral Nutrition Pump against defects in material and workmanship for a one (1) year period from date of delivery. This warranty is valid only to the original purchaser and does not extend to any product, or part thereof, that has been subjected to accident, alteration, abuse, misuse, or repair by other than Abbott authorized representatives, or has not been operated and maintained in the manner prescribed in the Operating Manual, or which at the time of pump failure was being used with pump sets or containers other than Abbott pump sets and containers. Examples of abuse or misuse include, but are not limited to, pumps that have been dropped, have had fluid spilled into or onto the casing, have been submerged or have had the back removed.

In no event shall Abbott be liable for any incidental, indirect, or consequential damages in connection with the purchase or use of the pump.

Abbott reserves the right to repair or replace (at its option) any pump that fails to meet the foregoing warranty.

THE WARRANTIES HEREUNDER ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE.

1 PRODUCT USE

2 THEORY OF OPERATION

3 PERFORMANCE VERIFICATION TEST

4 TEST AND INVESTIGATION

5 TROUBLESHOOTING AND REPAIR

6 REPLACEABLE PARTS AND REPAIR

7 EQUIPMENT AND TOOLS

8 REPLACEABLE PARTS LISTING

I

COMPANION PUMP

A volumetric infusion pump which uses a cassette with bellows to deliver measured amounts of enteral food

OPERATION

Range : 5 to 300ml/hr.

Accuracy : +/- 10% from 5 to 300ml/hr with zero back pressure.

Pressure : 168kPa (24psi) back pressure before occlusion.

Battery : 1Ah rechargeable sealed lead acid.
4 volt, recharge rate 1.5 hours for every 1 hour of battery use.
Capacity, when fully charged, 8 hours at 150 ml/hr.
Low battery, will run for approximately 30 minutes at 150ml/hr before shutting down completely.

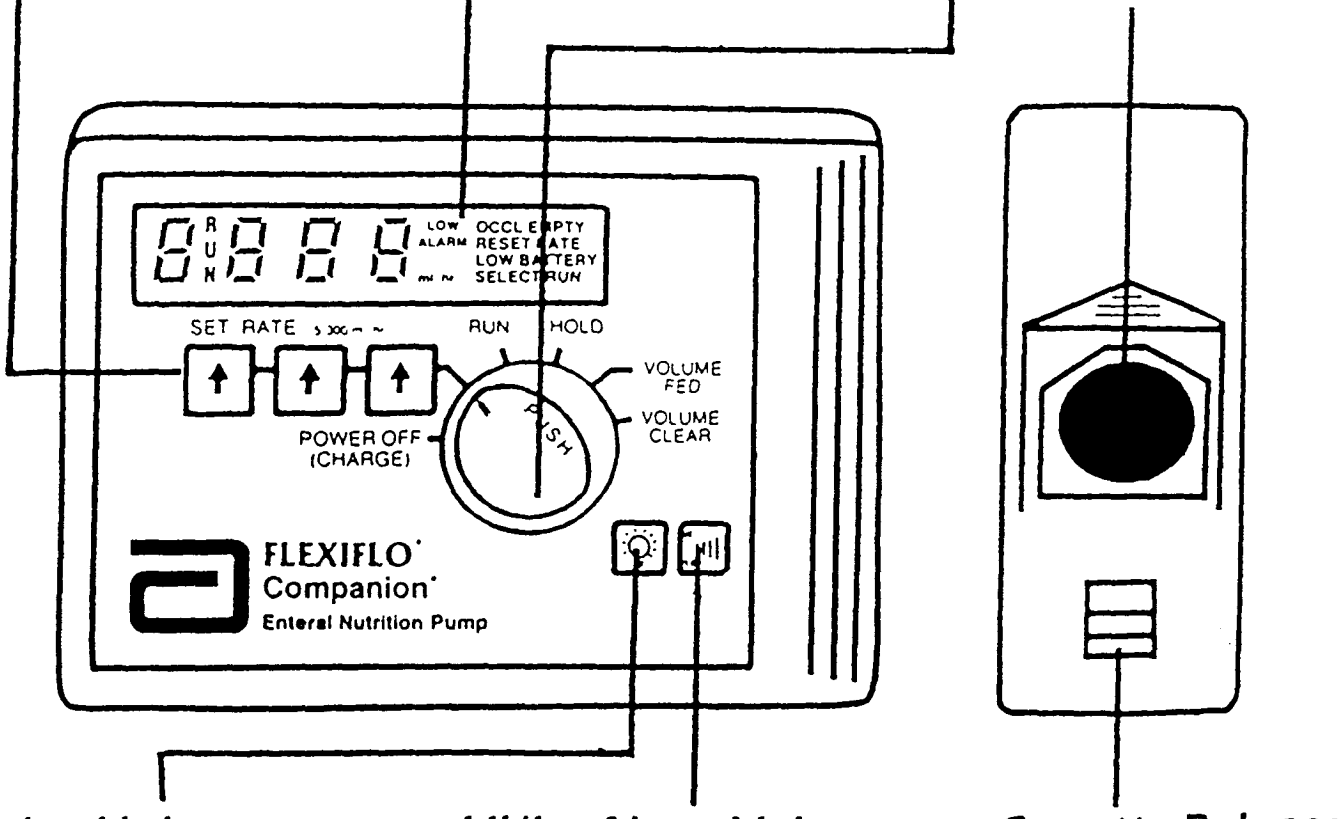
PUMP

Touch Pads:
Select the numerical value of flow rate from 5 to 300 ml/hr in 1-ml increments.

Display Panel:
Shows flow rate, accumulated volume, RUN indicator, visual explanation of all intermittent audio alarms.

Control: Select pump functions.

Cassette Cavity:
Insert cassette into pump, using shape orientation, until seated.



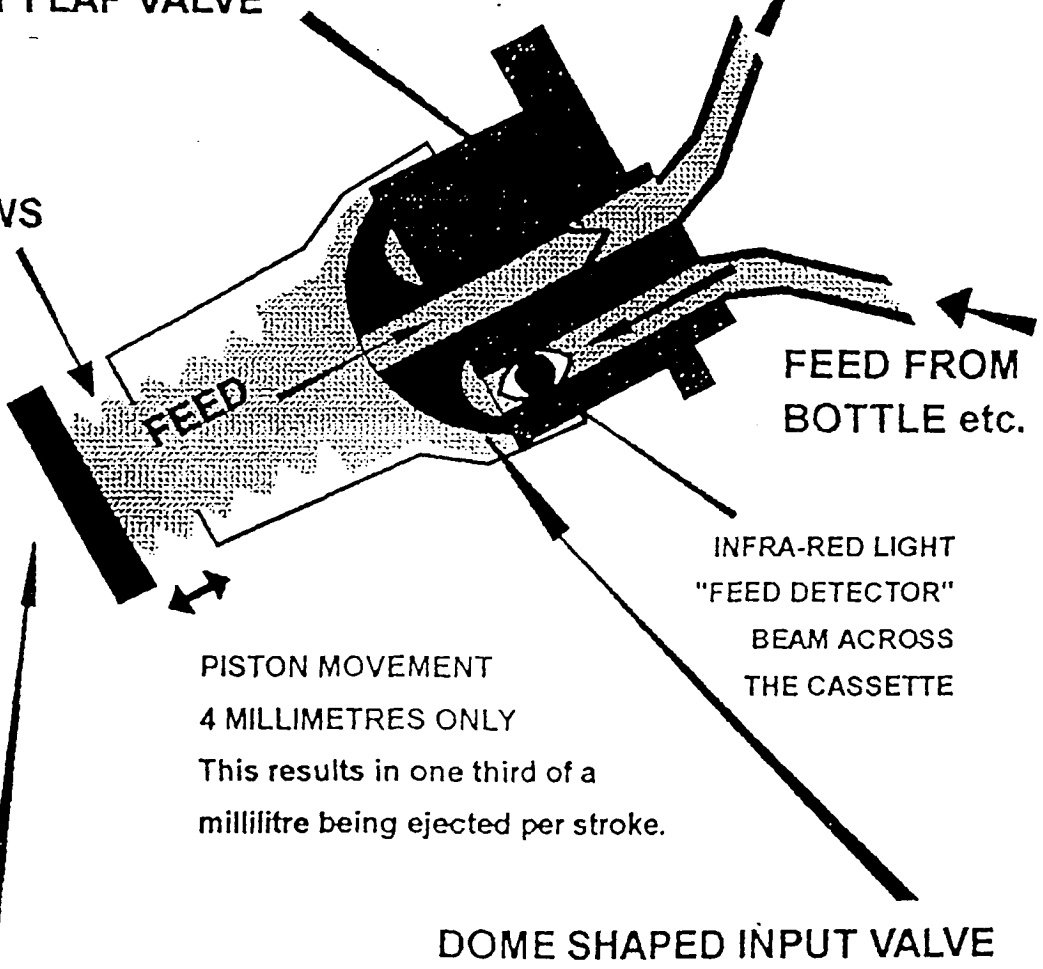
Display Light:
Press to temporarily illuminate display panel while on battery power.

Hi/Lo Alarm Volume:
Select volume of audio alarm.

Cassette Release Latch: Press dow release cassette fc removal.

PUMP SET

This is a simplified cross section view of the cassette when inside the pump.


TO PATIENT
OUTPUT FLAP VALVE
BELLOWS
FEED
FEED FROM BOTTLE etc.
INFRA-RED LIGHT "FEED DETECTOR" BEAM ACROSS THE CASSETTE
PISTON MOVEMENT 4 MILLIMETRES ONLY This results in one third of a millilitre being ejected per stroke.
DOME SHAPED INPUT VALVE
PUMP PISTON (+ PRESSURE SENSOR)

PRODUCT DESCRIPTION

Programming - 5 to 300 ml/hr increments

FEATURES

- Cassette Technology
- Alarms
  - Occlusion
  - Empty
  - Select Run
  - Low Battery
- Accuracy ± 10%

FEATURES

- 8 - Hour Battery Operation
- User Friendly Controls
- Backlight
- Self-Test
- Fluid Flow/Monitoring
  - independent of position

FEATURES

- Low/High Alarm
- Volume Fed Display
- Small and Light Weight
- Simple Set-Up
  - One hand cassette loading
- Ambulatory

PRACTICAL DEMONSTRATION

- ► Select Pump
  - Attach to Pole Stand
  - Plug in Power Card
- ► Set-Up Disposables/Prime Set
  - Fill feeding container/bag with enteral nutrition product
  - Suspend container to side/behind pump
  - Fill sight chamber 1/3 to 1/2 full

PRACTICAL DEMONSTRATION

- Remove cap from distal end of set
- Compress bellows of cassettes repeatedly (bellow facing downwards)
- Ensure all air is removed of bellow and set
- Insert cassette into pump

PRACTICAL DEMONSTRATION

- Pump Settings
  - Rate: 300 ml/hr
- Turn Control Dial to RUN
  Observe the following:
  - run/droplets icons
  - rate set is visible
- Turn Control Dial to HOLD
  Observe the following:
  - pumping stops

PRACTICAL DEMONSTRATION

- Turn Control Dial to VOLUME FED
  Observe the following:
  - Amount of feed delivered is displayed in mls
- Turn Control Dial to VOLUME CLEAR
  Observe the following:
  - Display shows 0000 ml
- Turn Control Dial to POWER OFF

ELECTRONIC PROBLEMS
(DETECTABLE DURING "SELF TEST" MODE)

When the control dial is rotated from the " **power off (charge)**" position to the " **set rate**" position, the five second " **self test**" **mode** is initiated. During the self test, verify that the following functions are initiated :

1 All seven of the four LCD numeric segments are displayed **(8888)** on the LCD.

2 All LCD indicators are displayed (**low battery, select run, reset rate, empty, occl, ml/hr, low alarm and run).**

3 The backlight illuminates **(two lamps).**

4 The audible beeper activates **(three consecutive high audible beeps).**

5 Verification of proper **RAM** and **I/O microprocessor functions.** Note, should there be an error associated with RAM ,the message **"F1" is** displayed on the LCD.

2

CASSETTE NOT PRESENT DETECTION

The pressure transducer is also used to detect the presence or absence of the disposable cassette within the pump cavity. If there is no cassette positioned within the pump cavity, the output of the transducer is **0 volts,** and the pump will indicate an "empty "visual and audible alarm.

FLUID EMPTY DETECTION

An infrared emitter diode and a silicon phototransistor are used in a thru beam configuration to detect the presence of, or lack of, fluid in the disposable cassette inlet chamber. If the cassette is pumped dry or there is an absence of fluid in the cassette inlet chamber, an "empty" visual and audible alarm is activated. Note, in order to conserve battery energy the infrared emitting diode is only activated during motor braking.

OCCLUSION SENSING AND ALARM

The pressure transducer is mounted at the end of the drive system cam follower (piston). During normal pumping, the piston remains in constant contact with the cassette bellows, producing an electric potential across the plates of the transducer. This signal varies in amplitude with the change in force required to compress the bellows. The flexiflow companion will pump against a back pressure of **168KPa (24 Psi)** before an occlusion alarm.

MOTOR RUNAWAY DETECTION BRAKE

The motor runaway detection (watchdog) circuit monitors the motor supply voltage, **Vm,** for conditions that may cause a motor runaway event by:

1 Verifying that **Vm** is activated for no more than 10 seconds.

2 At the end of each pumping cycle, the reed switch is magnetically triggered. The microcontroller disables the **run** line, and several milliseconds later, enables the **brake** line, stopping the motor abruptly.

When the brake line is enabled, the motor input is effectively short circuited. The back emf induced by the motor rotation allows it to stop very quickly. Note, the brake line is enabled for only a few milliseconds in order to conserve power and prolong battery life.

BATTERY

BATTERY AND CHARGING FEATURES

First

The battery regulates the charging voltage automatically requiring a single level constant voltage charging circuit.

Second

The battery is protected against excessive discharge by two separate circuits:

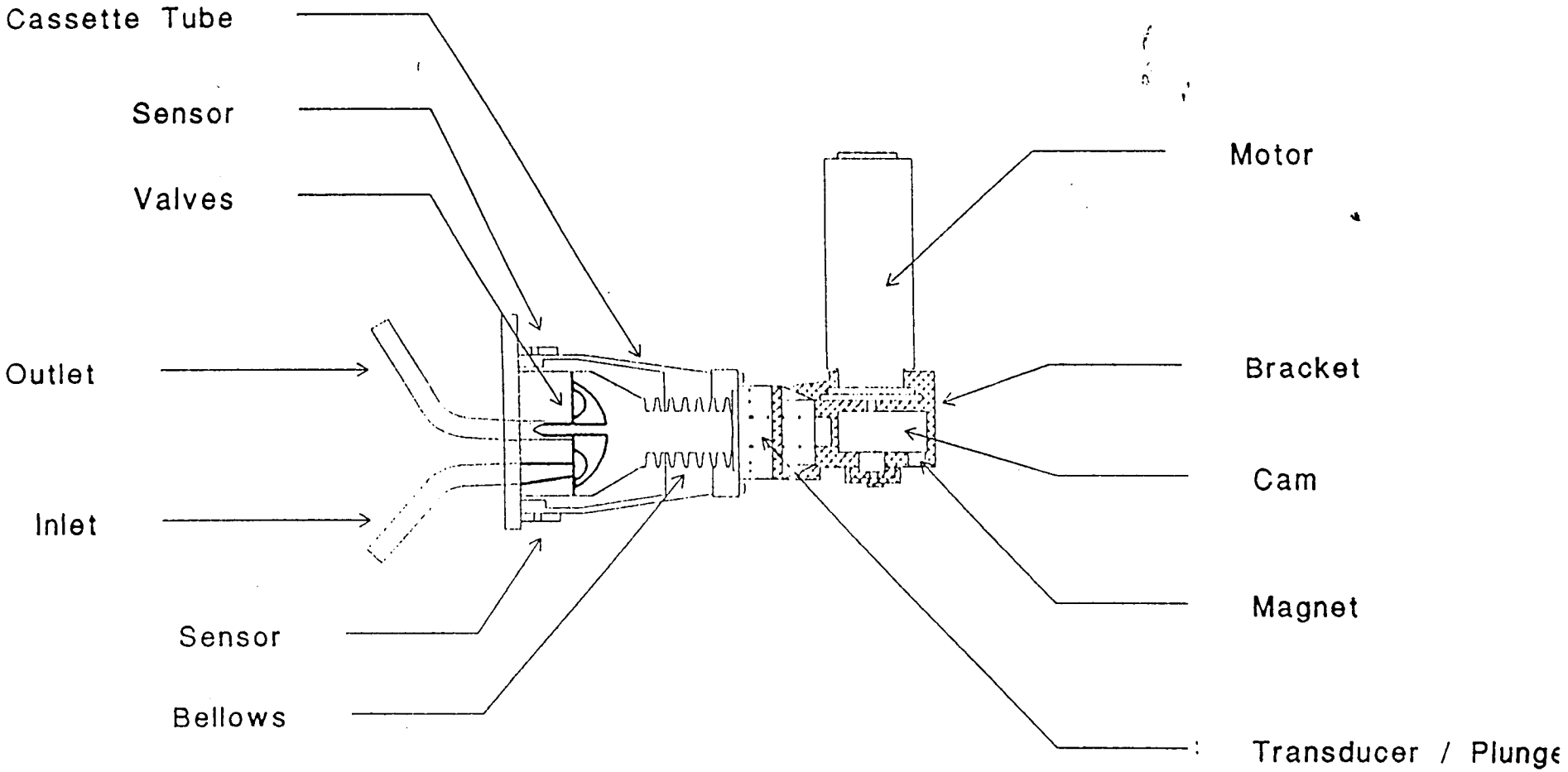
Circuit 1 detects when the battery voltage falls below **3.95 volts +/- 0.2** volts this circuit is called low battery detection.

Circuit 2 detects when the battery voltage falls below **3.65 volts +/- 0.2** volts this circuit is called low battery shutdown.

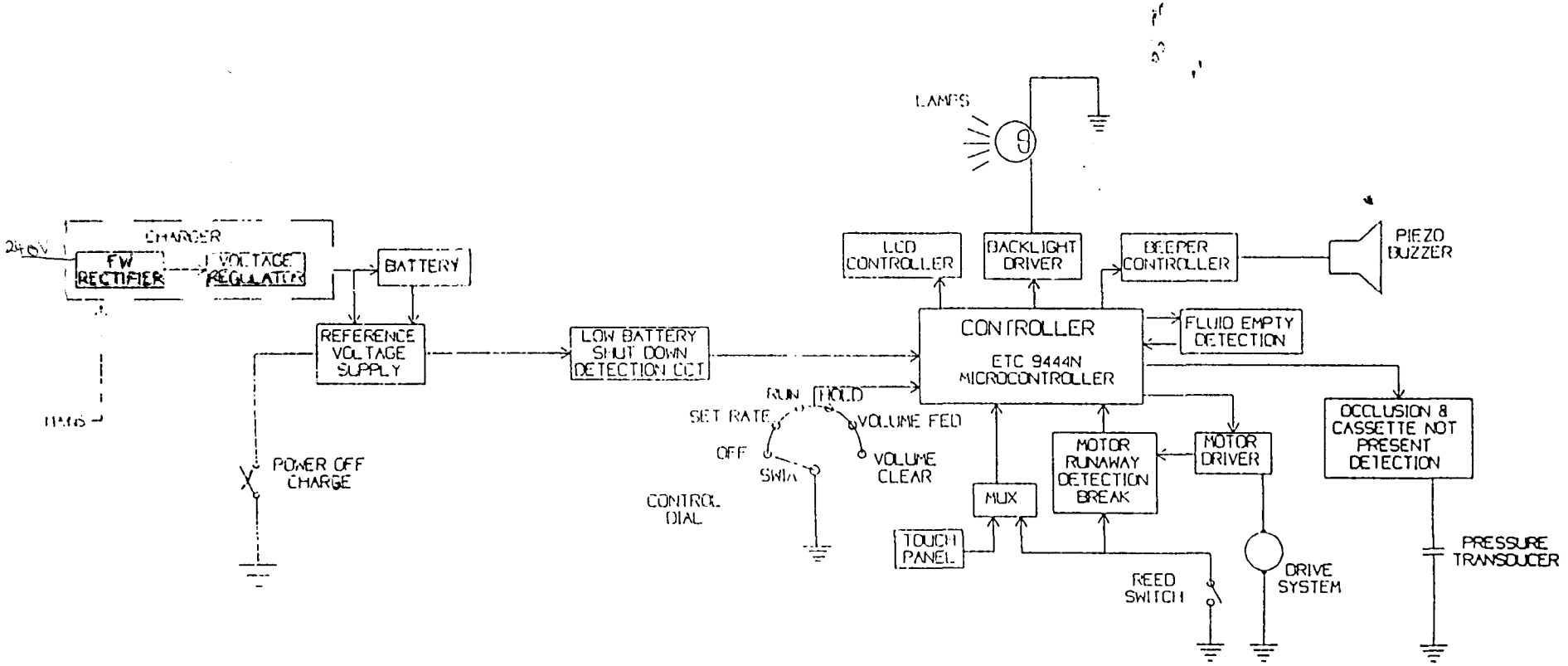
Third

The battery has an extremely low rate of self discharge, highly suitable for intermittent use.

FLEXIFLO COMPANION PUMP MECHANISM AND CASSETTE



COMPANION PUMP
FUNCTIONAL BLOCK DIAGRAM



FLEXIFLO COMPANION ENTERAL NUTRITION PUMP

THEORY OF OPERATION

- This pump replaces (or is a substitute for) peristaltic rotor/silicone tubing systems and syringe type infusion pump systems.
- It uses a cassette containing a compressible membrane and a pressure actuated combination check valve.
- The disposable cassette is inserted into the pump cavity with the compressible membrane contacting the drive system.
- Control and measurement of the administration of enteral feeding is monitored by a microcontroller.
- Enteral feeding can take place at rates of 5ml to 300ml per hour.
- The pump contains various sensors in order to detect flow alerting conditions (alarms).
- The pump is operated by mains power and also contains a sealed, rechargeable lead acid battery to allow portable operation by the pump.

CHARGER/POWER BOARD

- The power supply CCT is designed to operate at line voltages (220AC) providing a regulated output voltage of 5.15 VDC.
- This circuit provides enough power to operate the pump and charge the battery simultaneously.
- The power supply circuit consists of, input fuses, a stepdown power transformer (isolated), a full wave rectifier, an adjustable voltage regulator and output fusing.
- BATTERY:
  - A 4 volt, 1 amperehour rechargeable, sealed lead acid battery.
  - Optimum charging voltage is 4.6 VDC at 20 degrees Celsius.

REFERENCE VOLTAGES/SUPPLIES

* The pump is activated when the control dial is rotated to any position other than the "Power Off (charge)" position.

* At this point four separate voltage supplies are activated. (V^1, 1.2VRef, VBat, +V).

VBAT is directly supplied by the battery and/or charger. It is activated independently of the rotary switch position. It provides power to the motor drive and backlight circuits.

V^1: This voltage is provided when the pump is switched on. This voltage supply is the source of power to all IC packages in the pump, the alarm, the drop detector and the motor break circuits.

1.2V Ref: Is generated by a voltage regulator (LM3852Z-1.2). It supplies reference voltages to the empty occlusion, cassette missing and low battery/shutdown detection circuit.

+V: This voltage is produced at the collector of transistor Q3. It supplies power to the touchpanel overlay, reedswitch, multiplex, microcontroller, reset and display circuits. This voltage can be shut down by the low battery shutdown circuit to provide a fail safe pump shutdown.

LOW BATTERY/SHUTDOWN DETECTION

There are two separate circuits

One detects a battery voltage of less than 3.95 volts and activates the "Low Battery" alarms.

The other circuit, a battery voltage of less than 3.65 volts, automatically shuts down the pump. This prevents excessive battery discharge and protects the pumping circuitry.

Microcontroller (ETC9444N-XYH)

This is a single chip microcontroller containing 2K x 8 ROM and 128 x 4 RAM. It has 23 I/O lines which control and monitor various pumping and user interfacing functions.

Motor Driver

The motor driver circuit consists of a motor voltage regulator, which regulates the voltage supplied to the motor driver circuitry.

OCCLUSION AND CASSETTE NOT PRESENT DETECTION

A Piezoelectric ceramic transducer is mounted at the end of the drive system CAM follower. During normal pumping, the piston remains in contact with the cassette bellows, thus producing an electric potential across the plates of the transducer. IF this potential is greater than 1.2 volts (VRef) the audible and visible occlusion alarms are triggered.

This transducer is also used to monitor the presence of a cassette in the cassette tube. If there is no contact between the transducer and cassette bellows the output from the transducer will be 0 volts. Attempting to run the pump under these conditions will result in the "EMPTY" alarms being activated.

FLUID EMPTY DETECTION

A plastic infrared emitter diode and NPN silicone Phototransistor is used to detect the presence of, or lack of, fluid in the disposable cassette inlet chamber.

PUMP DISPLAY BOARD

This is a custom built transflective liquid crystal display (LCD). It provides information to the user on pump modes and alert functions. Data generated by the microcontroller is loaded into latches on this board. All necessary waveforms (normally square) supporting the display are generated on the board.

3

[illegible] International
[illegible] Service Procedure
Document SP-2002-01

Current Date: 04 Aug 1995 **Supercedes: 18 Jan 1995**

TITLE:
Performance Verificati[illegible] - Companion

Approvals:

Initiator:	Kevin Raymond	Date: 07 Feb 1995
AI Service Mgr.:	Lee Unuk	Date: 03 Aug 1995
AI QA:	Phil Wagner	Date: 03 Aug 1995
AISD:	S. J. Freeman	Date: 03 Aug 1995

Reference Documents:
RSC, MQA - 104

Reason for Revision:

Changes to Sections 3.0, 4.1 (B) & Page 6 Test Equipment List.

Rev. Level: B

ATTACHMENTS:
A Data Sheet

1.0 PURPOSE:

To set forth the Standard Test Procedure for Performance Verification Test of the COMPANION ENTERAL Pump.

2.0 SCOPE:

This procedure is for all Master Revision levels of COMPANION Pump.

3.0 EQUIPMENT:

1 - Stopwatch
1 - Empty Cassette
1 - Recirculating Cassette
1 - Multimeter
1 - Safety Analyzer

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4.0 PROCEDURE:

NOTE: All tests can be performed in any order as long as all testing is completed as required.

4.1 Visual Inspection:

(A) CHARGER UNIT

1. Verify that the Serial Number is present and all labels are correct and legible as per label log.

2. Verify that the charger has four (4) feet securely fastened to the bottom.

3. Verify the A.C. cord has no cuts or damage and is properly bound with a Velcro strap.

4. Verify the presence of a rubber pole clamp slot pad on applicable cases.

5. Examine the pole clamp assembly for proper function and damage.

(B) PUMP

1. Verify that the Serial Number and Master Revision are present and all labels are correct and legible as per label log.

2. Verify the faceplate is free of scratches and sharp edges. Also check for proper alignment and adhesion.

3. Verify ON/OFF button is secured and rotates with ease.

4. Verify the cassette holder is free of any foreign material.

5. Check the function at the release latch and its locking mechanism.

4.2 Functional Testing:

1. Place pump in charger unit and connect to A.C. outlet. Turn on the pump and verify positive contact with the charger unit. This can be verified by the backlight turning on. The word "BATTERY" is displayed if positive contact is not made. Disconnect charger from A.C

2. Engage and disengage the pump from the charger two or three times and observe the performance of the release latch at the rear of the charger. The pump should slide easily in and out of the charger.

3. Insert a water filled recirculating cassette into the cassette holder and observe the snap hold and release of the cassette latch.

4. Turn rotary switch to "SET RATE". Verify that the three (3) alarm tones sound and the following indicators are illuminated:

R	LOW	OCCL EMPTY
8u888	ALARM	RESET RATE
N		LOW BATTERY
	ML/HR	SELECT RUN

and then observe after the three (3) alarm tones have ended, the pump resets to "000 ML/HR BATTERY".

5. Test the ML/HR set rate buttons by depressing each one until a maximum of 300ML/HR has been reached.

6. Turn the rotary switch to the "RUN" position at 300ML/HR flow rate. The "RUN" indicator should flash. ONLY

7. Turn the rotary switch to the "HOLD" position. Verify the pump stops running and display indicates rate selected and "...."

8. Turn the rotary switch to "VOLUME FED" and observe the volume displayed.

9. Turn the rotary switch to "VOLUME CLEAR" and observe display resets to 000ML and BATTERY.

10. With the pump setting in any mode, push the LIGHT touch button on the display panel. Verify the light goes out within 15 seconds.

11. Remove cassette from cassette holder and allow pump to run at 300ML/HR. EMPTY alarm should flash within 15 seconds. Press LOW ALARM button on panel (bottom right), verify change in alarm volume.

12. With a rate of 300ML/HR insert an empty cassette into the pump, verify that EMPTY alarm activates and flashes within 45 - 60 seconds. Observe the following on display:

LOW ALARM	EMPTY
300ML/HR	BATTERY

13. Plug into A.C. outlet. Connect a digital volt meter to male D.C. output adapter on the charger. Verify a measurement of 5.11 to 5.15 volts under no load. Place a 15ohm, 5 watt resistor load across the multimeter and verify an output of 5.00 to 5.15 volts D.C. If the charger fails, adjust potentiometer (P301) on the power board for correct output voltage.

4.3 ELECTRICAL SAFETY TEST:

Leakage current shall be tested in accordance with IEC 601 standards.

A. Leakage Current

1) The pump shall be properly installed into the charger.

2) Because there are no exposed metal parts in the case which are likely to become energized, the leakage current is to be measured using the "metal foil" technique.

3) A piece of metal foil with an area not exceeding 10 by 20 centimeters (200 square centimeters) shall be placed in intimate contact with an accessible surface of the charger case. The foil shall be located by experimentation so that the current to ground is maximum.

4) The leakage current is to be measured between power (earth) ground and the foil in contact with the enclosure for any combination of the following conditions:

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a) electrical supply polarity normal and reversed;
b) power switch on and off;
c) ground open and intact.

5) The maximum allowable leakage current, under any of the above conditions, is 50 microamperes (AC rms).

B) **Ground Impedance**

N/A. No externally accessible ground, therefore no ground impedance measurement is mandated.

4.4 DELIVERY ACCURACY TEST:

Prime set with a common enteral fluid. Set-up pump with fluid container 25" ± 5" above cassette holder and distal end of set 18" ± 5" below cassette holder. Place distal end in a graduated cylinder. Set pump rate to 100 ML/HR. Turn rotary switch to "RUN". After 30 minutes turn rotary switch to "HOLD". Observe volume in VOLUME FED position and volume in graduated cylinder. Spec is 45.0 to 55.0 mL.

4.5 OCCLUSION TEST:

Using the same set up as Section 4.2, turn rotary switch to "RUN". Occlude set at distal end. Observe "OCCL" alarm activates and flushes within 70 seconds.

4.6 BURN-IN:

Insert a primed water filled recirculating cassette into the pump and set rate at 300ML/HR. Run COMPANION pump for one hour. Verify no problems after this time, sign and pass Performance Verification Test.

END OF DOCUMENT

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1. With a set rate of 30[illegible], clamp off distal end, OCCLUSION should flash within 70 seconds _____SECS.

4.6 Burn-In

1. At a set rate of 300M[illegible], run pump for one hour problem free _____HR.

PVT PASSED_____FAILED_____

Performance Verification Test Performed by:_____Date:_____

Test Equipment:
Safety Analyzer:_____
DMM #_____
Recirculating Cassette #_____
Empty Cassette #_____
Stop watch #_____

** End of Document **

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[illegible] Sheet
[illegible] ent A

List Numbers:_____ Version ____) Serial Number:_____

4.1 Visual Inspection

(A) CHARGER UNIT

1. Serial number and labels are present and legible	PASS_____	FAIL_____
2. Verify the presence of 4 rubber feet on bottom	PASS_____	FAIL_____
3. Inspect electrical cord for cuts or damage	PASS_____	FAIL_____
4. Verify the presence of rubber pole clamp pad (if applicable)	PASS_____	FAIL_____
5. Verify proper function of pole clamp assembly	PASS_____	FAIL_____

(B) PUMP

1. Serial number and labels are present and legible	PASS_____	FAIL_____
2. Verify faceplate is free of damage	PASS_____	FAIL_____
3. Verify function of ON/OFF rotary switch	PASS_____	FAIL_____
4. Check the function of cassette release latch	PASS_____	FAIL_____
5. Verify no foreign material in cassette holder	PASS_____	FAIL_____

4.2 Functional Testing

1. Connect charger to A.C. and verify positive contact is made with charging circuit and BATTERY is displayed	PASS_____	FAIL_____
2. Confirm smooth action between pump and charger connection	PASS_____	FAIL_____
3. Verify function of cassette release latch	PASS_____	FAIL_____
4. Verify startup display and alarm tone	PASS_____	FAIL_____
5. Verify function of touchswitch arrows	PASS_____	FAIL_____
6. Verify the RUN indicator upon starting pump	PASS_____	FAIL_____
7. Verify the pump stops, selected rate and BATTERY are indicated when put to HOLD	PASS_____	FAIL_____
8. Verify ML/HR diplays	PASS_____	FAIL_____
9. Verify Volume Clear operation, resets to 0000mL and battery	PASS_____	FAIL_____
10. Verify light operation	PASS_____	FAIL_____
11. Verify LOW ALARM operation	PASS_____	FAIL_____
12. Verify EMPTY ALARM operation	PASS_____	FAIL_____
13. Charger output (Spec. = 5.00 to 5.15 VDC with load	_____	VDC
(Spec. = 5.11 to 5.15 VDC no load	_____	VDC

4.3 Electrical Safety Test

Leakage Current (<50 uA) _____ mA

4.4 Accuracy Test

1. Volume delivered (45.0 - 55.0 mL) _____ mL

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4.5 Occulsion Test

4

TEST AND INVESTIGATION OF A COMPANION PUMP

CLEANING AND MAINTENANCE DO'S AND DON'TS

Do clean the pump, don't submerge, heat, steam or radiate sterilise.

CLEANING FLUIDS

- Dishwashing Detergent
- Isopropyl Alcohol
- 10% concentration of 5.25% Sodium Hyrochloride (household bleach)

CLEANING

- Separate pump from charger
- Clean outside surfaces
- Clean pump cavity (do not use *alcohol* on pump cavity)
- Clean cassette latch
- Slide pump back into charger

TEST AND INVESTIGATION

Charger Case:

- Examine Charger Case for Cracks
- Examine all Labels
- Connect to AC Power
  - Check Mains Neon
  - Check DC output 5.13 to 5.15 Volts
  - Check with a 15 ohm load, > 5.00 volts

TEST & INVESTIGATION CONT'D

- Insert an empty cassette and run the pump at 300ml/hr "CASSETTE EMPTY" alarm should occur withing 70 seconds
- Run the pump at 300ml/hr and observe "EMPTY" alarm after 2 rev's
- Run the pump at 300ml/hr with a blocked cassette "OCCLUSION" alarm should occur within 70 seconds

TEST & INVESTIGATION CONT'D

PUMP:

- Functionally check the operation of the pump on AC and DC
- Examine the pump case for damage
- Check all labels
- Check the function of the main switch and all Touchpanel switches
- Check the operation of the cassette latch
- Examine the display
- Remove case screws (3 rear) and remove the switch cover. Remove nut and washer from switch. Split pump case

15

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
1. "OCCL" alert does not activate when a downstream occlusion condition is present	A. Faulty feeding set	A. Replace faulty feeding set.
	B. Poor connection, between transducer and main pc board assembly (connector PL6/J6)	B. Reseat pressure transducer connector (PL6) onto the main pc board connector (J6). Inspect connectors for damage.
	C. Occlusion sensor is in need of calibration (P2)	C. Recalibrate occlusion sensor circuit.
	D. Faulty occlusion sensor (pressure transducer)	D. Replace defective pressure transducer (Piston/Cap assembly) Recalibrate occlusion sensor circuit.
	E. Faulty occlusion sensor Circuit (U2, U4, P2)	E. Replace main pc board assembly,
2. "OCCL" alert activates when a downstream occlusion condition is not present	A. Faulty Feeding set.	A. Replace faulty feeding set.
	B. Occlusion sensor is in need of calibration (P2)	B. Recalibrate occlusion sensor circuit.
	C. Faulty occlusion sensor (pressure transducer)	C. Replace defective pressure transducer (piston/cap assembly) Recalibrate occlusion sensor circuit.
	D. Faulty occlusion sensor circuit (U2, U4, P2)	D. Replace main pc board assembly. Recalibrate all alarm detection circuits.

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
3. "OCCL" (cass. not present) alert fails to activate when the cassette is not present within the pump cavity.	A. Occlusion sensor is in need of calibration (P2)	A. Recalibrate occlusion sensor circuit.
	B. Faulty occlusion sensor (pressure transducer).	B. Replace defective pressure transducer (piston/cap assembly) Recalibrate occlusion sensor circuit.
	C. Faulty occlusion circuit (U2, U4, P2, P3)	Replace main pc board assembly.
4. "OCCL" (cass. not present) alert activates when there is a cassette present within the pump cavity.	A. Faulty feeding set	A. Replace faulty feeding set.
	B. Poor connection between pressure transducer and main pc board assembly (connector PL6/J6)	B. Reseat pressure transducer connector (PL6) onto the main pc board connector (J6). Inspect connectors for damage.
	C. Occlusion sensor is in need of calibration (P2)	C. Recalibrate occlusion sensor circuit.
	D. Faulty occlusion sensor (pressure transducer)	D. Replace defective pressure transducer. Recalibrate occlusion sensor circuit.
5. "EMPTY" alert fails to activate when the feeding set is empty of Enteral product.	A. Enteral Product visible within the cassettes inlet tubing	Allow enteral product to be pumped totally beyond the cassette. Note: No product must be visible within the inlet tubing of the cassette.
	B. Faulty Feeding Set	B. Replace Faulty Feeding Set.

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
9. "LOW BATTERY" alert does not activate when battery is low (battery capacity below 40%)	A Faulty low battery detention circuit (U1, RP3, R4)	Replace main pc board assembly. Recalibrate all alarm detection circuits.
10. "LOW BATTERY" alert activates when battery has been well charged.	A. No power at AC receptacle during changing.	A. Verify proper 220V, operation at AC receptacle.
	B. Faulty charger circuit or DC power connector.	B. Verify proper 5.15VDC operation at charger output connector. Replace faulty charger.
	C. Low or dead battery life	C. Replace battery.
	D. Faulty DC power jack	D. Replace faulty DC power Jack
	E. Poor connection of battery terminals onto DC power clips	E. Inspect and reseat battery terminals onto DC power clips.
	F. Poor connection between power connector and main pc board assembly (connector PL1/J1)	F. Reseat power connector (PL1) onto the main pc board connector (j1). Inspect connector for damage.
	G. Faulty battery charging circuit (D1)	G. Replace main pc board assembly.
11. When battery is low, pump goes directly into low battery shut-down (by-passing "LOW BATTERY" alert)	A. Faulty low battery/ low battery shutdown circuit (U1, Q2, Q3, D2, R3, R4, RP3)	A. Replace main pc board assembly.
12. Pump fails to go into low battery shut-down, when battery is very low (battery capacity below 15%)	A. Faulty low battery shutdown circuit (U1, Q2, Q3, D2, R3, RP3)	A. Replace main pc board assembly.
13. Motor rotates without a pause and pump goes into a shut-down mode (audio will sound continuously).	A. Poor connection between reed switch and main pc boards assembly (connector PL6/J6)	A. Reseat the reed switch connector (PL6) and main pc board connector (J6). Inspect connector for damage.

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
	B. Faulty reed switch	B. Returned for level 3 repair
	C. Pump in the presence of equipment having strong magnetic field	C. Remove pump from immediate area.
	D. Faulty motor drive circuit (U1, U5, Q4, D7)	D. Replace main pc board assembly.

MISCELLANEOUS ELECTRONIC PROBLEMS

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
1. Nothing happens when the pump's rotary dial is in a position other then "POWER OFF (Charge)"	A. Low battery power level	A. Recharge (by inserting pump into charging unit)
	B. Dead Battery	B. Replace only with battery marked 2A x 2K (4V, 1.0Ah)
	C. Poor connection of battery terminals onto DC power clips	C. Insert and reseat battery terminals onto DC power clips
	D. Poor connection between power connector and main pc board assembly (connector PL1/J1)	D. Reseat power connector (PL1) onto the main pc board connector (J6). Inspect connectors for damage.
	E. Faulty power switch (SW1)	E. Replace main pc board assembly.
	F. Faulty supply circuit (U1, Q1, Q2, Q3.)	F. Replace main pc board assembly.
2. One of more touch panel pads do not respond when depressed.	A. Poor connection between touch panel overlay connector and main pc board assembly (connector PL5/J5)	A. Inspect and reseat touch panel overlay connector (PL5) onto the main pc board connector (J5). Inspect for damaged or cracked overlay ribbon cable.
	B. Faulty touch panel overlay	B. Replace faulty touch panel overlay.

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
	C. Faulty [illegible]	C. Replace main pc board assembly.
3. Battery life is too short (falls well short of 8 hour operating battery life)	A. Insufficient [illegible] recharge time	A. Allow pump to charge (in charger) for 12 to 15 hours.
	B. No or low power at AC receptacle during charging	B. Verify proper 220V, operation at AC receptacle.
	C. Faulty charger circuit	C. Verify proper 5.15 VDC operation at charger output connector. Replace faulty charger.
	D. Low or dead battery	D. Replace battery. Note: Replace only with battery with battery (4V, 1.0Ah).
	E. Faulty low battery detention circuit (U1, RP3, R4.)	E. Replace main pc board assembly.
4. Charger operates warmer than normal	A. Incorrect routing of DC power connector subassembly	A. Inspect routing and connection between the DC power connector and power pc board assembly.
	B. Faulty power pc board assembly	B. Replace faulty power pc board assembly. Recalibrate the charger output.

PUMP TROUBLESHOOTING MECHANICAL AND ELECTRICAL

1. Take a pump.

2. Remove from charger if required.

3. Check main control switch for functionality by switching on and off using On/Off tool.

4. Switch pump to the set position. Check touchpanel buttons for functionality. Replace touchpanel if buttons don't work or if panel is damaged. If the display is scrolling then you must also replace touchpanel. This is done when reassembling the pump after troubleshooting.

   ☞ *You will be instructed when to change touchpanel later in the procedure*

   ☞ *If switch is not functioning properly or is not properly connected then replace. See procedure for switch replacement (TR-309). Change switch after uncasing pump*

5. Check front and back case of pump for cracks or damage.

   ☞ *If cases are cracked these will have to be replaced later in the procedure when pump is opened*

   ☞ *If during self test the pump does not give 3 alarms or alarm sound is distorted, then replace. See procedure for Piezo alarm replacement (Ref. TR- 310). Replace when pump in uncased*

6. Remove 3 Philips screws from the rear of the pump.

7. The battery cover can be removed by slapping the pump's back onto your hand. The cover should pop out of place. Lift out using small flat head screwdriver if required.

   7.1 Remove battery and place in a labelled container for recharging.

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8. The nut holding the front case on should be found under the control knob. This can be loosened using the 3/8" or 5/16" hex driver depending on nut size.

9. The nut and washer must now be removed.

   This can be done by turning the pump over and shaking. Both should fall out.

10. The main switch pin may have to be pushed to one side to remove the nut and washer.

    The pin can be moved using the needle nose pliers.

11. Before pulling the front and back cases apart to open pump, make sure the pump is in the OFF position for older cases and in the SET position for new case design.

    ☞ ***This is done to avoid pulling the switch away from PCB during pump opening***

12. Pull front and back case apart by placing left thumb inside cassette tube, holding it against the front case and using your right hand to pull back case away from it.

13. Cases should be split apart first at the cassette tube.

    ☞ ***Watch that main control switch is clear of case. Once this is done the rest can be pulled apart***

    The touchpanel plug and socket will pull apart when cases are opened.

14. If it has not been already done PL6 should be disconnected from J6.

    ☞ ***Replace back or front case at this stage if required. See procedure for front and back case replacement (TR 306)***

15. The cases can be laid out flat with the front case face down and the back case with its back facing down.

16. Cleaning optics: Clean optics in cassette tube using prepared dishwater detergent in plastic container. Dip cotton swab in this solution and wash the inside of cassette tube opening. Use air gun to clear optics openings.

17. Next remove cassette latch.
    This is done by pulling it at the end furthest from the cassette tube away from the case.

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18. The latch is discarded.

19. Clean or scrape area where latch moves using an Exacto knife.

20. For pumps with stiff latches any excess plastic on the cases which may inhibit the movement should be scratched away.

21. Replace latch into front case.

22. This is best done by placing the cassette holding lip on the latch into the cassette tube.

23. Then push down on the latch on the lip for operating the latch and simultaneously with the right hand push back the flap on the latch which causes the spring action. This flap clips behind the plastic holder on the front case.

24. Check latch for functionality. It should have a free springing action. If it does not spring then remove and re-clean.

☞ ***A shiny surface will appear on the case where latch is catching. Scrape away excess plastic in these areas***

25. Check revision of main PCB.

If board contains R43 with a value of 1.2 Ohm no upgrade is needed. This is an Epic board. No up-grade is needed.

If the pump contains Avx board with R8 and R8 of value 1 Ohm, with resistor 1.2 from R8 to J2 connector no upgrade is required.

If the pump contains Avx board with no R43 and with R7 of value 2.2 Ohm, this must be upgraded

To upgrade see procedure on Main PCB upgrade (Ref. Section TR 307).

26. Next connect jumper from PL6 to J6.

27. Connect 5.15 volt DC supply to the pump via DC power jack.

28. Switch the pump to the OFF position using ON/OFF tool.

29. Connect scope to TP3 and ground on the pump using the 10:1 probe.

30. Set scope to scope mode. See procedure for scope set-up (TR-322).

31. Select Setup 1.

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31. Securely locate primed cassette into pump cassette tube.

☞ *This cassette should be blocked at end of tube to simulate blocked pipe.. No more than 6 inches from end of tube*

32. Turn pump control switch to the set position and set delivery to 300ml/hr. This is done by shorting pins 1 & 2 of J5.

33. Turn switch to run position and observe signal on Oscilloscope.

☞ *The max peak voltage should be between 1.43 and 1.47 volts. This sets downstream occlusion alarm*

34. Adjust pot 2 to get required signal max peak 1.45 ± 0.02 volts.

35. Replace transducer if voltage cannot be adjusted.

☞ *If signal has noise of spurious spikes this could be caused by grit or dirt on motor cam or set contains air bubbles*

Reprime set or clean motor cam as required using alcohol

If signal still isn't clear then transducer should be replaced

See procedure for transducer replacement (TR 311).

36. Set pot 2 for new transducer to get required voltage between 1.44 and 1.52 volts.

☞ *Run pump with blocked cassette. It should occlude within 70 seconds. Record this result on DHR system*

37. Next connect probe of Oscilloscope to TP 6.

37.1 Select setup 2 (Ref TR-322)

38. Remove primed cassette from cassette tube.

☞ *This next test is to set pump to detect cassette empty. The signal and voltage have to be recorded when the pump is in the self test mode after switch on*

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39. Switch pump from "Power OFF" position to ON/"SET Rate" or any power up position.

40. The pump will alarm and carry out a self test.

    During this test the peak voltage and signal should be observed on the scope meter.

    ☛ ***The signal should be a square pulse and the voltage peak should be between 3.6 and 3.7 volts.***

41. Adjust P1 to get correct voltage 3.6 volts.

    ☛ ***The voltage should only be read during the self test mode. When voltage is adjusted insert empty cassette and set pump to 300 ml/hr. Run pump. Pump should flash cassette empty within 70 seconds. Record this result on DHR system***

42. Some older boards will contain a test point TP4. This point is to the left of the main switch. This point is to the left of the main switch. This is for testing motor speed. If the pump has not got a TP4, connect to pin 9 or 10 on U3.

43. Connect 10:1 probe to TP4 or pin 9 or 10 on U3.

44. Run pump at 300ml/hr, by shorting out pins 1 and 2 of J5.

45. Observe pulses on scope.

46. The space between pulses should be 4 seconds. See Attachment F(1).

47. Measure this time using the cursors on the scope. It should read 4.00.

48. Set the pump to run at 150mL/hr by shorting pins one, two and three as required on J5.

49. When the pump is running observe the signal on the scope meter.

50. Again, as before, check time for the cycle of the motor.

51. The cycle time (dt) should be 8.00 seconds.
    See Attachment F(2).

52. If this is not the cycle times, then replace the motor (Ref. TR-311).

53. Replace the motor if signal is distorted.

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54. Re-check pulse space after motor replacement.

☛ *Place torque seal on P1 and P2 after adjustments are finished*

55. Next check that reed switch and motor are working.

56. Set pump to run at 300ml/hr by shorting pins 1 and 2 of J5.

57. Switch main control switch to the run position.

58 If motor runs slowly then replace. See motor replacement procedure (TR 311).

59. If motor runs but doesn't stop when passing the reed switch after every revolution then the reed switch or magnet on the motor cam needs replacing.

60. First check wire connection from reed switch to J6. If connection is OK then the problem is in the Cam magnet or the reed switch.

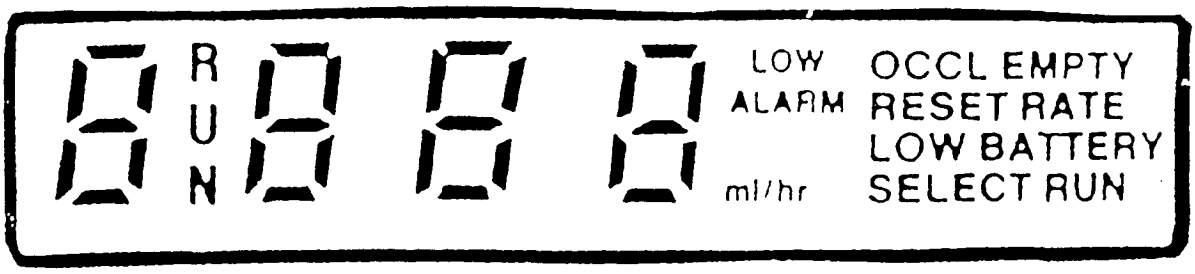
61. Run motor again and use a hand held magnet to simulate the motor magnet by bringing it close to the reed switch for every revolution of the motor.

62. If the motor now stops then the motor magnet must be weak. Replace motor. See motor replacement procedure (Ref. TR 311).

63. If motor continues to rotate without stopping then reed switch needs replacing.

64. See procedures for (reed switch) front case replacement since reed switch is part of front case (Ref. TR 306).

65. Now check display by switching pump from off to on positions. During a self test all legends should appear clear on LCD display as follows:



Note: In the case of an icon display. The alarms are replaced by Icons

66. If LCD is damaged or does not display clearly then see procedure for LCD cleaning (and replacement) (Ref. TR 312)

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67. If back lights to the left and right of the LCD do not light up during self test, replace them. See procedure for back light replacement (Ref. TR 312).

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68. Remove 10:1 scope probe, jumper lead and DC power supply cable from pump.

69. Check main control switch pin.

70. If damaged remove using needle nose pliers, holding switch firmly while pulling it out.

71. To insert new pin hold pin with snips in left hand.

72. Insert to start of pin hole.

73. Squeeze through pin hole with needle nose pliers held in right hand.

74. Use an air gun to remove any excess scrapping or debris from pump.

75. To re-assemble pump and cases set pump to the "Set Rate" position for new case design and to the off position for older cases.

76. Hold back and front case and assemblies in left hand so that the ends containing the cassette tube are facing upwards.

77. Using push pull spring hook push the red wire carrying power from the battery, and the black and red wire from the motor, under the LCD display so they are not lying on the LCD display or entering the battery chamber.

78. Bring case together at battery chamber end and then gently bring together at the cassette tube end.

79. Re-connect PL6 to J6.

80. Push case together. Be careful not to damage main control switch and pin.

81. Check that the case fits together properly and that there are no large gaps between cases.

82 Insert main control switch washer and nut with needle nose pliers avoiding damage to switch pin.

83. Screw on using 3/8" or 5/16" hex driver depending on nut size.

☞ ***Care is needed in tightening nut since damage to switch is possible from over tightening***

84. Replace 2 Philips screws in back case.

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85. Replace touchpanel at this stage if required. This will have to be done for new front cases.

See touchpanel replacement procedure (TR 313).

86. Connect panel plug to J5 on the main PCB board. This is done by looking at the plug through the battery chamber. The plug should be held using a needle nose pliers and pushed onto J5. Insert good recycled battery into battery chamber with contacts of battery in line with contacts of pump.

87. To put back battery cover, insert end of cover with lip into the base of back case at the bottom of the battery at an angle of approximately 90 degrees to its holding position.

88. When the lip on the cover slips into place under the battery, fold the cover over into place and fix in position using a washer and Philips screw.

89. Check if the pump revision number has to be changed and change if required. Reference "Companion Pump Model Changes".

90. Switch the pump from Off to "Set Rate" position.

91. Check that the touchpanel works, display works and that the battery is working.

92. Do the same checks with 5.15 DC voltage supply.

93. Back light should stay ON when using DC voltage power supply.

94. Push back main control switch cup into position.

95. Check cassette latch functionality.

96. Set pump to run at 300ml/hr.

97. Pump should flash "Empty" after two revolutions of motor.

98. Record any parts issued and repair codes on DHR system.

99. <u>REFERENCES</u>

Companion Pump Model Changes
Q-009 - The Finisklin DHR Management System.
M-008 - Repair and Recalibration of all Companion pumps
TS-001 - Electronic DHR System - Operation.
TMC-004 - Material allocation to work order.

100 <u>REASON FOR REVISION</u>

Rev. 1: General update.
Rev. 2: Frantz Medical Recommendations
Rev. 3: To change occlusion voltage settings in section 3.3, 3.4.
Rev. 4: (a) Inserted Risk column into Hazard Analysis section.
(b) Deleted Rev. date from all pages but the first page.

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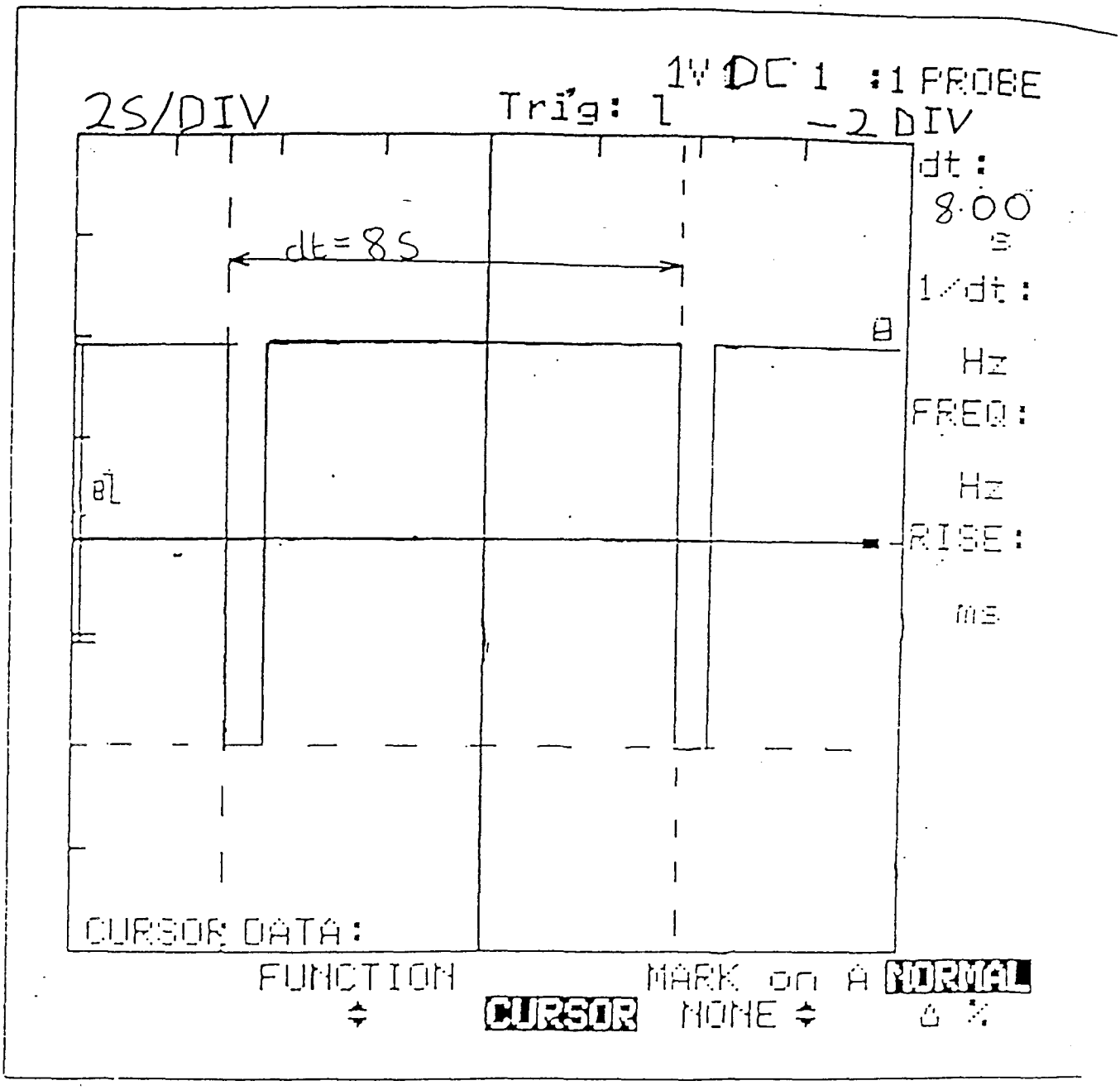

DELAY = -2

The dt value is the time between the two cursors.

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ATTACHMENT F2

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9

To Repair Charger

- Remove Case Screws (4)
- Replace Neon if necessary
- Check for circuit problems , fuses, transformer AC socket and wiring.
- Adjust output with P301 to 5.15 Volts and check that voltage remains above 5.00 volts under a 15 ohm load.
- Apply a sealant to P301 to secure.
- Reassemble the charger.

PUMP REPAIR

Parts Replacement (Motor)

- Disconnect motor connector (J2)
- Lift out motor / cassette tube assembly
- Turn cassette tube to separate
- Examine the motor and gearbox for smooth rotation
- Replace with new motor / gearbox if necessary
- Reassemble

Parts Replacement (Transducer& Cassette Tube)

- Remove 2 screws at end of cassette tube
- Disconnect grey and red wires from PL6
- Pull the wires free
- Remove the transducer and bracket
- Use AMP crimping tool to reassemble wires to PL6.
- Replace cassette tube if necessary.
- Reassemble wires to cassette tube as before.
- Reassemble transducer and bracket.
- Reassemble Motor assy to transducer
- Reconnect to main PCB
- Re-seat LCD if necessary

Cassette Latch

- This may be repaired or replaced
- Repair involves detailed cleaning of the latch and surrounding case areas to ensure free operation of the latch.
- Remove excess plastic from the case.
- Replacement recommended (100%)

Touchpanel

- Lift one corner of old Touchpanel with a knife or screwdriver. Use a pliers to pull the Touchpanel from the case.
- Remove any remaining adhesive.
- Place a switchcup in the case for alignment
- Remove the main backing sheet from the Touchpanel.
- Place the connector through the case and align the Touchpanel around the switch cup. The switchcup should move freely.
- Remove small piece of backing at bottom and position Touchpanel.

Battery Replacement

- Remove the battery cover from the rear of the pump.
- Slide out the old battery.
- Slide in the new battery
- Replace only with Sonnenschine 4V/1AH battery or approved equivalent.
- Replace battery cover

DISASSEMBLY INSTRUCTIONS FOR COMPANION PUMP AND GENERAL

Disassembly and reassemble of the Flexiflo Companion Enteral Nutrition Pump is accomplished with the hand tools indicated in Section 7. Unless otherwise noted, reverse disassembly procedure for assembly.

Caution: Remove all power from the instrument prior to disassembly or reassembly. Prior to returning a repaired pump or charger for patient use, both units must undergo all checkout procedures outlined in Section 4.3 and the appropriate recalibration outlined in Section 4.5.

Note: Due to static sensitive components, it is recommended that service personnel wear an anti-static wrist strap (or other grounding means while servicing the Flexiflo Companion Pump.

PUMP DISASSEMBLY PROCEDURE

1. Removing Battery Access Door

a) Remove Phillips screw and washer on battery access door and remove door.

2. Remove Battery

a) Remove battery access door.
b) Slide battery out through access hole.

3. Removing Control Dial Assembly

a) Push control dial to the open position.
b) Pull the control dial door in order to remove control dial assembly.

4. Remove Back Case

a) Remove control dial assembly.
b) Remove 5/16" nut and washer from rotary dial switch.
c) Remove battery
d) Remove 2 remaining Phillips screws and separate back-case assembly to expose connectors.
e) Disconnect the 7 pin ribbon cable (PL5)
from the main pc board connector.
f) Disconnect the 8 pin MTA connector (PL6)
from the main pc board connector
g) Fully separate the back and front case while carefully sliding the motor and power wires from between the main and display pc board assemblies.
h) Disconnect the display pc board from the main pc board by squeezing the ends of each of the 4 stand off while lifting up on the four corners of the display pc board.
i) Disconnect the 2 pin MTA connector (PL2) from the main pc board connector (J2).
j) Remove the positive (+) battery clip from the front case by sliding it off the locating boss.

5. Removing Piezo Beeper

a) Remove back case
b) Disconnect the 2 pin MTA connector (PL4) from the main pc board connector (J4)
c) Gently remove the piezo beeper by peeling it off the main pc board assembly (Item 18)

6. Removing DC Power Jack

a) Remove back case
b) Slide the DC power jack from the locating notch in the back case.
c) Remove the negative (-) battery clip from the back case by sliding it off the locating boss.
d) Disconnect the 4 pin MTA connector (PL1) from the main pc board connector (J1).

7. Removing Main PC Board

a) Remove back case
b) Remove piezo beeper
c) Remove DC power jack
d) Remove 5 Phillips screws/washers
e) Lift main pc board from back case

8. Removing Drive System

a) Remove back case
b) Remove cassette retaining switch
c) Rotate cam so that the piston is in the forward-most position.
d) Carefully peel the reed switch from the front case. Note: The reed switch may have to be replaced due to damage during removal.
e) Lift pump cavity and slide drive system from front case.

9. Removing Piston/Cap (Pressure Sensor)

a) Remove drive system
b) Detach cassette tube from motor bracket by twisting 90 degrees and pulling apart.
c) Remove 2 Phillips screws holding the adapter bracket to the cassette tube.
d) Separate adapter bracket and pump cavity and remove the piston/cap subassembly.

10. Removing Front Touch Panel

a) Peel front touch panel from the front case
b) When reassembling, clean front case (bonding surface) with alcohol in order to remove old adhesive.
c) Clean LCD glass with alcohol.
d) Replace with a new front touch panel.

CHARGER DISASSEMBLY PROCEDURE

1. Removing Rear Cover

a) Remove 4 corner Phillips screws on rear cover and separate from front housing.
b) Disconnect the DC power connector, 1/4" push on receptacles from the power pc board, 1/4" tabs marked J303 and J304.

2. Removing Power PC Board

a) Remove 4 Phillips screws from power pc board
b) Remove the power cord, green wire, ring terminal by first removing the 1/4" nut and Phillips screw that supports the power transformers.

3. Removing Pole Clamp

a) Remove rear cover
b) Remove 2 Phillips screws centrally located on rear cover.
c) Lift clamp tube containing the pole clamp mechanism, from rear conversion.
d) Slide pole clamp mechanism form clamp tube.

4. Removing DC Power Connector

a) Remove rear cover
b) Remove Phillips screw on release plate.
c) Lift release plate from front housing and carefully remove the DC power connector.

Equipment List

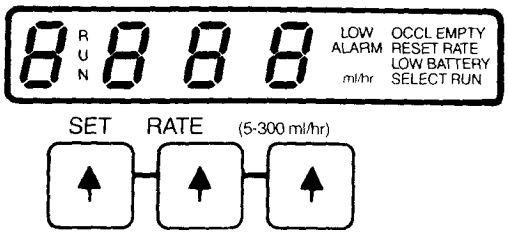
- Fluke 97 Scopemeter or equivalent
- DMM
- Companion Sets and cassettes
- Osmolite or Ensure.
- Various leads and load resistor
- Stopwatch
- AMP Crimping Tool
- Screw drivers, Pliers, Snips, Nut Drivers, Pot adjuster, Spring hook etc.

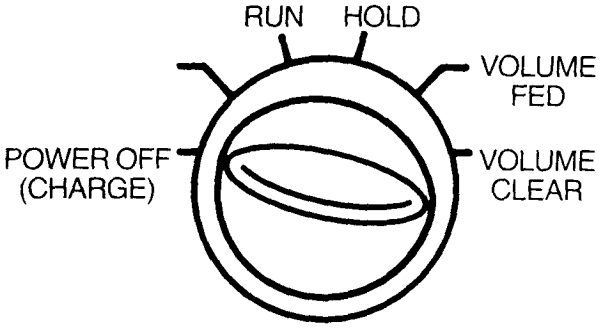
8

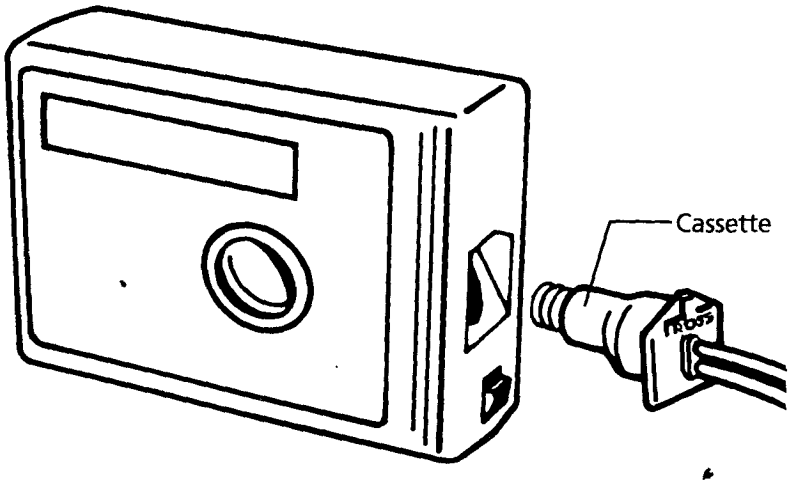
DESCRIPTION	PART NO.	SELLING PRICE
VELCRO STRAP	100007	A$25.16
LABEL ALARMS	200061	A$3.45
LABEL INSTRUCTION	200064	A$3.45
LABEL PUMP ID	200067	A$3.45
LABEL DANGER	200068	A$3.45
ADAPTER BRACKET	300006	A$24.15
BATTERY DOOR	400014	A$29.97
WINDOW	400015	A$9.80
PUMP FRONT CASE	400017	A$45.79
PUMP REAR CASE	400018	A$76.38
CASSETTE RETAINING SWITCH	400019	A$17.10
RUBBER FEET	400027	A$1.20
PLATE	400029	A$14.65
CHARGER FRONT HOUSING	400030	A$76.38
CHARGER REAR HOUSING	400057	A$76.38
DRIVER GASKET	400068	A$5.00
DISPLAY PCB ASSEMBLY	500017	A$238.13
BATTERY,4V-1AH	500018	A$84.38
PIEZO BEEPER	500020	A$25.16
TRANSDUCER	500023	A$67.50
DC POWER JACK	500024	A$17.50
REED SWITCH	500025	A$12.50
DC POWER CONNECTOR	500033	A$16.25
MAIN PCB ASSEMBLY	500048	A$157.37
POWER PC BOARD	500049	A$155.79
APPLIANCE RECEPTACLE	500087	A$11.50
MAINS INDICATOR	500092	A$30.98
OVERLAY	500093	A$99.81
MOTOR CAM ASSY	List No 447	A$188.59
CASSETTE TUBE OPTICS ASSY	List No 448	A$44.74
CONTROL KNOB ASSY	List No 449	A$39.19
POLE CLAMP ASSY	List No 458	A$75.84
COMPANION SERVICE MANUAL	List No 469	A$134.40

Flexiflo® Companion®

Enteral Nutrition Pump







Call toll free **1-800-231-3330** to inquire about service for your device. Be prepared to provide device name, serial number found on back and specifics of problem.

For additional information, refer to the official Operating and Repair Manuals.

Abbott Critical Care Systems
SME. Service Centre
Abbott Australasia Pty. Ltd.
Captain Cook Drive, Kurnell
NSW 2221 Australia
Tel. 1800 819 831, (02) 9668 1816

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OPERATION CHECKLIST

To determine if Pump is in working order

(Check as completed)

- ☐ With Pump in Charger, plug in cord and turn on Pump.
- ☐ Start self-test by turning control dial to SET RATE position. Display reads 8888 and messages appear. Alarm sounds. Note: If any messages stay on, note this and send Pump and Charger in for servicing.
- ☐ Press each UP arrow until display reads 299.
- ☐ Turn control dial to RUN. Flashing RUN message is displayed.
- ☐ Listen near the pump cavity for the sound of pumping action.
  Note: Without a cassette in place, EMPTY alarm is triggered if test is not completed in about 45 seconds.
- ☐ Turn dial to HOLD position. Pumping action will stop.
- ☐ Insert a cassette into pump cavity until it snaps in. Use cassette release latch to remove cassette.
- ☐ Release Pump from Charger, using pump release latch. Return Pump to Charger and be sure they snap together firmly.
- ☐ Optional: Test for flow-rate accuracy using directions in Operating Manual.

BEFORE SENDING PUMP IN FOR SERVICE

- ☐ Did you clean Pump and Charger as directed?
  Yes ( ) No ( )
- ☐ Did you follow Operation Checklist as directed?
  Yes ( ) No ( )
- ☐ What do you think is wrong with this Pump and/or Charger?

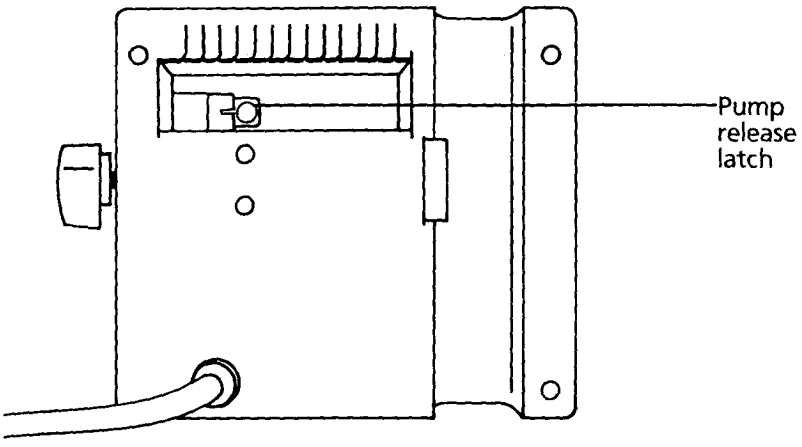
_____

_____

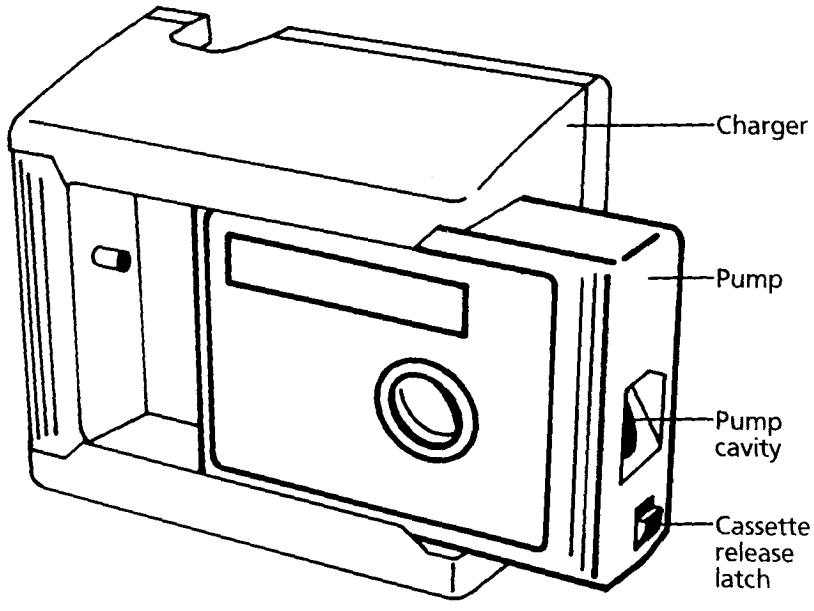
Send this sheet in with Pump an[illegible]arger when returning for service. Be su[illegible] both Pump **and** Charger togethe[illegible]

USA

Flexiflo® Companion®
Enteral Nutrition Pump



Back



Front

PREVENTIVE MAINTENANCE PROCEDURE

1 Perform at regular intervals
2 Perform before sending in for service

Cleaning

- Do not submerge or autoclave Pump or Charger.
- Turn off Pump and unplug Charger.
- For general cleaning, use dishwashing detergent (non-chlorine-based) or isopropyl alcohol.
- For disinfecting after exposure to AIDS or Hepatitis, use 10% concentration of 5.25% sodium hypochlorite (household bleach). After exposure to Tuberculosis, use 70% concentration isopropyl alcohol. These recommendations are not substitutes for official procedures that may differ among institutions.

Housing

(Check as completed)

- ☐ Using pump release latch, separate Pump and Charger.
- ☐ Clean outside surface of Pump and Charger with warm, soapy water. Rinse. Let air-dry.

Pump Cavity

- ☐ Clean pump cavity with a cotton swab or soft cloth and warm, soapy water. DO NOT USE ALCOHOL. Dry thoroughly. Be sure no soap film or residue is left in pump cavity.
- ☐ Clean cassette release latch with alcohol. Move latch up and down to be sure it moves freely.
- ☐ Slide Pump into Charger until it snaps into position.

Laboratories